

Please amend the present application as follows.

IN THE CLAIMS

Please amend claim 14 so that it reads as follows:

C1 Claim 14 (amended) An expression vector according to claim 13 wherein said transmembrane domain comprises residues 229 to 251 of SEQ ID NO:2.

Remarks

Rejection of the Claims under 35 U.S.C. §§101/112

Claims 1-19 have been rejected under 35 U.S.C. §§101/112 first paragraph. Applicants respectfully traverse the rejection of these claims.

The present application contains abundant utility for the claimed *Zcytor11* polynucleotide, the *Zcytor11* protein that it encodes and the antibodies that specifically bind to the *Zcytor11* protein.

**A. The Claimed Polynucleotides have Utility Because They Bind Near a Disease-Associated Portion of Chromosome 1.**

The final utility guides published on January 5, 2001 in Vol. 66 No. 4 of the Federal Register, contains a number of comments. The last sentence of comment 4 on page 1095 states,

“A claimed DNA may have a specific and substantial utility because, *e.g.*, it hybridizes near a disease-associated gene or it has a gene-regulating activity.”

Page 23 lines 4-15 of the specification states:

“*Zcytor11* maps 84.62 cR from the top of the human chromosome a linkage group on the WICGR radiation hybrid map. The use of surrounding markers positioned *Zcytor11* in the 1p35.2 to 35.1 region.

## BEST AVAILABLE COPY

Thus Zcytor11 could be used to generate a probe that could allow detection of an aberration of the Zcytor11 gene in the 1p chromosome, which may indicate the presence of a cancerous cells or a predisposition to cancerous cell development. This region of chromosome 1 is frequently involved in visible deletions or loss of heterozygosity in tumors derived from the neural crest cells particularly neuroblastomas and melanomas.

Thus, applicants have shown that the *Zcytor11* DNA hybridizes near a disease-associated gene. Thus, according to the comments promulgated by the Commissioner of Patents, this is a specific and substantial utility.

### **B. The Claimed Polynucleotides Possess Utility Because They Encode a Useful Protein**

On page 27, lines 24-27, the specification teaches that Zcytor11 is expressed in pancreas with low levels in colon, small intestine and thymus. The receptor mRNA localization suggests that Zcytor11 may regulate gastrointestinal, pancreatic or thymic functions. Thus, the Zcytor11 polypeptide can be used to produce antibodies, which then can used to identify or separate these tissues. THIS IS A REAL WORLD, WELL ESTABLISHED UTILITY. The use of antibodies to Zcytor11 to tag cells is specifically disclosed on page 22 lines 24-25 of the specification.

This is evidence that the antibodies to the Zcytor11 polypeptides have a SPECIFIC UTILITY, because not all tissue types express the Zcytor11 receptor, and SUBSTANTIAL UTILITY, because it is important that biologists be able to separate specific cell types for further study or therapeutic re-implantation into the body. Thus, the antibodies are being used for their unique properties that can be used immediately by scientists for the unique properties of the antibodies. Thus, the Zcytor11 polypeptide has utility because it is needed to produce the antibodies, and polynucleotides that encode the Zcytor11 polypeptide have utility because they can be used to produce the polypeptides that produce the antibodies.

### **C. The Claimed Polynucleotides Can be Used to Tag Chromosomes**

Another well established utility that the antibodies have is that they can be labeled, generally with fluorescence, and a surgeon can apply them to a surgical field to

# BEST AVAILABLE COPY

determine whether or not all of the tissue that is need to be excised is excised. Specifically, antibodies to Zcytor11 can be labeled with fluorescence and applied to the surgical field after the surgeon has removed a pancreas to be certain that all of the pancreatic tissue has been removed. This is a **WELL-ESTABLISHED UTILITY**, which is **SPECIFIC** and **SUBSTANTIAL**. This is yet another reason why the antibodies to the Zcytor11 polypeptide, the Zcytor11 polypeptide, and the polynucleotides that encode the Zcytor11 polypeptide possess utility.

Labeled polynucleotide probes of SEQ ID NO: 1, or corresponding RNA or antisense polynucleotides can be further used as chromosome tags to tag chromosome 1 as is described by Example 4 pages 27-28 of the specification. This is another specific and substantial utility. Labeled polynucleotide probes of SEQ ID NO: 1 can also be used to identify the tissues listed in the specification that express Zcytor11.

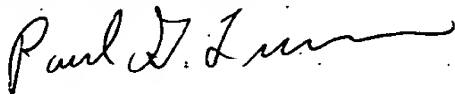
The utilities of the claimed invention described above provide immediate benefit to the public. That is all that is required under 35 U.S.C. §101. Applicants request that the rejection of Claims 1-19 be withdrawn and the claims allowed.

## **Rejection of the Claim 14 under 35 U.S.C. §112 second paragraph**

Claim 14 has been amended as the Examiner has suggested. Applicants request that the rejection under 35 U.S.C. §112 second paragraph be withdrawn.

Based upon the arguments previously submitted, Applicants submit that claims 1-19 are in condition for allowance. Applicants request that all rejections be withdrawn and the claims allowed.

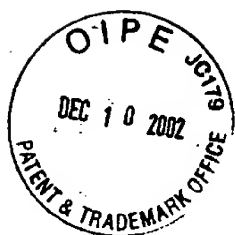
Respectfully submitted,



Paul G. Lunn, Esq.

Reg. No: 32,743

(206) 442-6627



Marked-up Page showing  
amendment of <sup>30</sup>claim 14

RECEIVED

DEC 12 2002

TECH CENTER 1600/29

BEST AVAILABLE COPY

11. An expression vector comprising the following operably linked elements:
- a transcription promoter;
  - a DNA segment encoding a ligand-binding receptor polypeptide, said polypeptide being defined by amino residues 18 to 228 of SEQ ID NO:2; and
  - a transcription terminator.
12. An expression vector according to claim 11 wherein said polypeptide further comprises a signal sequence.
13. An expression vector according to claim 11 wherein said polypeptide further comprises a transmembrane domain.
14. An expression vector according to claim <sup>13</sup>~~11~~ wherein said transmembrane domain comprises residues 229 to 251 of SEQ ID NO:2.
15. An expression vector according to claim 13 wherein said polypeptide further comprises an intracellular domain.
16. An expression vector according to claim 15 wherein said intracellular domain comprises residues 252 to 574 of SEQ ID NO:2.
17. An expression vector according to claim 11 wherein further comprising a DNA sequence encoding an affinity tag.
18. An expression vector according to claim 17 wherein the affinity tag is an immunoglobulin F<sub>c</sub> polypeptide.
19. A transformed or transfected cell into which has been introduced an expression vector according to claim 11, wherein said cell expresses a receptor polypeptide encoded by the DNA segment.